

TABLE—EUP MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS—Continued

Test guideline No.	Data requirement	All use pat- terns	Test substance		Test notes
			MP	EP	
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI.	
830.6303	Physical state	R	TGAI	TGAI.	
830.6304	Odor	R	TGAI	TGAI.	
830.6313	Stability to normal and elevated tem- peratures, metals, and metal ions.	R	TGAI	TGAI.	
830.6317	Storage stability	R	TGAI and MP	TGAI and EP.	
830.6319	Miscibility	R	MP	EP	5
830.6320	Corrosion characteristics	R	MP	EP	6
830.7000	pH	R	TGAI	TGAI.	
830.7100	Viscosity	R	MP	EP	7
830.7300	Density/relative density/bulk density (specific gravity).	R	TGAI	TGAI

(d) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit microbial pesticides product analysis as referenced in the last column of the table contained in paragraph (c) of this section.

1. If an experimental use permit is being sought, and if the pesticide is not already under full-scale production, a schematic diagram and/or description of the manufacturing process suffices.

2. If an experimental use permit is being sought, and if the product is not already under full-scale production, a discussion of unintentional ingredients is required to be submitted to the extent this information is available.

3. Required for each isolate of a microbial pesticide. Isolates must be deposited with an agreement to ensure that the sample will be maintained and will not be discarded for the duration of the associated experimental use permit(s).

4. Required to support registration of each manufacturing-use product and end-use product. This analysis must be conducted at the point in the production process after which there would be no potential for microbial contamination or microbial regrowth. For pesticides in the production stage, a preliminary product analytical method and data would suffice to support an experimental use permit. For full registration, generally an analysis of samples is a compilation of batches, over a period of time, depending on the frequency of manufacturing.

5. Only required for emulsifiable liquid forms of microbial pesticides.

6. Required when microbial pesticides are packaged in metal, plastic, or paper containers.

7. Only required for liquid forms of microbial pesticides.

[72 FR 61002, Oct. 26, 2007, as amended at 77 FR 52613, Aug. 30, 2012]

§ 158.2172 Experimental use permit microbial pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test appear in (d) of this section, and the procedures appear in paragraph (e) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides residue. The test notes are shown in paragraph (d) of this section.

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TABLE—EUP MICROBIAL PESTICIDES RESIDUE DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Pat-terns	Test Sub-stance Data to Sup-port MP or EP	Test Notes
885.2100	Chemical Identity	CR	EP	1
885.2200	Nature of the Residue in plants	CR	EP	1
885.2250	Nature of the Residue in animals	CR	EP	1
885.2300	Analytical methods - plants	CR	TGAI	1
885.2350	Analytical methods- animals	CR	TGAI	1
885.2400	Storage Stability	CR	EP	1
885.2500	Magnitude of residue in plants	CR	EP	1
885.2550	Magnitude of residues in meat, milk, poultry, eggs	CR	EP	1
885.2600	Magnitude of residues in potable water, fish, and irrigated crops	CR	EP	1

(d) *Test notes.* The following test note is applicable to the data requirements for experimental use permit microbial pesticides residue as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required when the results of testing:
 - i. Indicate the potential to cause adverse human health effects or the product characterization indicates the microbial pesticide has a significant potential to produce a mammalian toxin; and
 - ii. The use pattern is such that residues may be present in or on food or feed crops.

§ 158.2173 Experimental use permit microbial pesticides toxicology data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the toxicology data requirements for a particular microbial pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (d) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not re-

quired; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for microbial pesticide toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PESTICIDES TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Pat-terns	Test Sub-stance	Test Notes
885.3050	Acute oral toxicity/pathogenicity	R	TGAI	1
885.3150	Acute pulmonary toxicity/pathogenicity	R	TGAI	--
885.3200	Acute injection toxicity/pathogenicity/ (intravenous) Acute injection toxicity/pathogenicity/ (intraperitoneal)	R	TGAI	2
885.3400	Hypersensitivity incidents	R	All	3
885.3500	Cell culture	R	TGAI	4
870.1100	Acute oral toxicity	R	MP, EP	1, 5
870.1200	Acute dermal toxicity	R	MP, EP	5
870.1300	Acute inhalation toxicity	R	MP, EP	5, 6
870.2400	Acute eye irritation	R	MP, EP	5
870.2500	Primary dermal irritation	CR	MP, EP	5

(d) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit microbial pesticides toxicology as referenced in the last column of the table contained in paragraph (c) of this section:

1. The acute oral toxicity/pathogenicity study is required to support the TGAI. However, it can be combined with the unit dose portion of the acute oral toxicity study, with an EP or MP test material to fulfill the requirement for the TGAI and the MP or EP in a single study, if the new protocol is designed to address the endpoints of concern.